UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,773	09/29/2006	Hiroshi Inooka	66368(46590)	3641

21874 7590 12/24/2008

EDWARDS ANGELL PALMER & DODGE LLP
P.O. BOX 55874
BOSTON, MA 02205

EXAMINER	
LI, RUIXIANG	
ART UNIT	PAPER NUMBER
1646	
MAIL DATE	DELIVERY MODE
12/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,773	INOOKA ET AL.	
	Examiner	Art Unit	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *8,9 and 11-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 10, and 14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/15/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of species GLP-1 in claim 10 as an endogenous ligand and metabolic disease in claim 15 as a target disease in the reply filed on 10/15/2008 is acknowledged. Claims 1-7, 10, and 14-16 are currently under consideration. All other claims are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/15/2008.

Information Disclosure Statement

2. The information disclosure statement filed on 05/15/2007 has been considered by the Examiner and a signed copy of the form PTO-1449 is attached to the office action.

Drawings

3. The drawings filed on 09/26/2006 are accepted by the Examiner.

Priority

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections—35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claim 16 is rejected under 35 U.S.C. §101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" context of use for the claimed invention which does not require further research.

Claim 16 is drawn to a method for the prophylaxis and/or treatment of a disease in a mammal, wherein an increased blood concentration and/or a prolonged blood half-life of an endogenous ligand and/or is effective for the prophylaxis and/or treatment of the disease, comprising administering to the mammal an effective amount of an antibody that has an affinity to the endogenous ligand but does not neutralize the same substantially, so as to increase the blood stability of the endogenous ligand, thereby enhancing a receptor activity-regulatory action. The determination of the utility of the claimed invention is limited to the method of treatment of a disease. Since the method does not specify a specific disease, the claimed method does not have a specific and substantial utility.

7. Claim 16 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections—35 USC § 112, 2nd paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 2 and 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 16 are indefinite because they recite "a receptor activity-regulatory action". It is unclear what the metes and bounds of the limitation are.

Claims 14 and 16 use the ambiguous language "and/or", rendering the claims indefinite. In addition, the claim language of claim 14 is so ambiguous that the claim fails to particularly point out and distinctly claim the subject matter. Claim 15 is rejected as a dependent claim from claim 14.

Claim Rejections—35 USC § 102(b)

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-7, 14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Frincke et al. (US Patent No. 5,055,289, Oct. 8, 1991).

Frincke et al. teach a method for treating viral diseases and tumors in an animal comprising administering to the animal an effective amount of an endogenous ligand, interferon, and an antibody that binds the interferon at a site which does not substantially impair its therapeutic activity and which extends the serum half-life of the interferon (see, e.g., claim 11). Frincke et al. teach that interferon has a therapeutic effect in the treatment of certain malignant tumors including breast cancer (column 4, lines 8-12). Binding of the antibody to the interferon did not inhibit the anti-viral property (column 4, lines 66-68) or anti-proliferative activity (column 5, lines 5-7) of the interferon.

Frincke et al. teach that when alpha-interferon:IFG252.2 complex administered to rats, the serum half-life of interferon was twelve times longer than when alpha-interferon was administered alone, 84 minutes versus 6.8 minutes (column 5, lines 29-47). The blood concentration of the interferon when alpha-interferon:IFG252.2 complex was administered was about seven times higher than when alpha-interferon was administered alone (50,000 u/ml x min versus 7,047 u/ml x min; column 5, lines 38 and 46).

Thus, the reference of Frincke et al. meets the limitations of claims 1-7, 14, and 15.

12. Claims 1-7, 10, 14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamaguchi et al. (WO 91/12022, August 22, 1991), as evidenced by Frincke et al. (WO 85/00974, March 14, 1985).

Hamaguchi et al. teach a method for improving the blood stability of IL-2 in rat comprising administering intravenously to the rat an effective amount (a dose equivalent to 100 μg of the rhIL-2) of an immune complex of anti-IL-2 monoclonal antibody and IL-2 (Experimental Example 1, page 39). The serum rhIL-2 concentration was about 7 times higher than when rhIL-2 was administered with a control antibody (page 39, line 20-22). The specific activity of the immune complex per rhIL-2 was identical to that of rhIL-2 itself (page 36, line 3-7). The blood half-life is far less that one week (Fig. 3). Hamaguchi et al. also teach that administering the immune complex of anti-IL-2 monoclonal antibody and IL-2 enhanced anti-tumor effects in mice (Experimental Example 4).

Hamaguchi et al. teach various immune complexes of an antibody (bottom of page 14 to top of page 15) and a cytokine, such as interferon (page 10, line 19) or a hormone, such as calcitonin (page 11, line 17). Hamaguchi et al. further teach that such an immune complex can be used to treat various diseases such as cancer or hormone control abnormality (page 3, 1st paragraph; bottom of page 27 to the 2nd paragraph of page 30).

Hamaguchi et al. further teach an immune complex of a monoclonal antibody and α-interferon prolonged the blood half-life (bottom of page 5 to top of page 6) by twelve times as evidenced by Frincke et al. (WO 85/00974, column 5, lines 29-47).

Thus, the reference of Hamaguchi et al. meets the limitations of claims 1-7, 10, 14, and 15.

Claims Objection—Minor Informalities

13. Claims 1-7, 10, and 14-16 are objected to because of the following informalities:

(i). Claim 1 has a typographic error in line 1: "An method" should be amended as "A method".

(ii). Claim 7 is incomplete.

(iii). Claim 1-6, 10, and 14-16 recite non-elected endogenous ligands, whereas claims 14-16 are objected to because they recite non-elected diseases.

Appropriate correction is required.

Conclusion

14. No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/
Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.
December 21, 2008